DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CANCER INSTITUTE
22nd Meeting
DIRECTOR'S CONSUMER LIAISON GROUP
Natcher Conference Rooms E1/E2
NIH Bethesda, Maryland
January 6 - 7, 2003
Summary of Meeting

The 22nd meeting of the National Cancer Institute (NCI) Director's Consumer Liaison Group (DCLG) was convened at 8:10 a.m., January 6, 2003, at the Natcher Conference Center, National Institutes of Health (NIH), Bethesda, Maryland. Ms. Barbara LeStage presided as Chair.

DCLG Members:

Ms. Barbara K. LeStage, Chair
Ms. Vernal Branch
Ms. Susan Butler
Ms. Kathy Giusti
Mr. Michael Katz
Ms. Ruth Lin
Ms. Gena Love
Mr. Chris Pablo
Ms. Karen Packer
Mr. Henry Porterfield
Ms. Nyrvah Richard (absent)
Mr. Doug Ulman
Dr. Marisa Weiss

Speakers:

Dr. Andrew von Eschenbach, Director, NCI
Dr. Ann Barker, Deputy Director for Strategic Scientific Initiatives, NCI
Ms. Nancy W. Buelow, Council of Public Representatives, NIH
Ms. Nina Ghanem, Communications Coordinator, Office of Liaison Activities (OLA), NCI
Ms. Brooke Hamilton, Consumer Advocates in Research and Related Activities, (CARRA) Program Coordinator and Professional Societies Liaison, OLA, NCI
Ms. Debra R. Lappin, Esq., Council of Public Representatives, NIH
Dr. Joseph Lipscomb, Chief, Outcomes Research Branch, NCI
Ms. Cynthia Morgan, Ethics Office, NCI
Ms. Kathie Reed, Office of Science Planning and Assessment, NCI
Dr. Julia Rowland, Director, Office of Cancer Survivorship, NCI

NCI Staff

Dr. Alan Rabson, Deputy Director, NCI
Ms. Elaine Lee, DCLG Executive Secretary, Office of Liaison Activities (OLA)
Ms. Elisabeth Handley, Acting Director, OLA
Ms. Jennifer Gorman Vetter, NIH Public Liaison Officer and Director's Council (Council of Public Representatives (COPR)) Coordinator
Ms. Nancy Caliman, DCLG Liaison, OLA
Ms. Keisha Martin, Program Assistant for DCLG, OLA
Ms. Linda Ticker, Administrative Program Assistant, OLA
Ms. Heather Williams, NCI Intern

OPEN MEETING

I. WELCOME AND SELF-INTRODUCTIONS

Opening Remarks. Ms. Barbara LeStage welcomed participants to the 22nd meeting of the DCLG and asked members to introduce themselves. She noted that the DCLG's current process of organizational change is difficult and time-consuming, but will produce a more focused and effective advisory committee.

Ms. Elisabeth Handley introduced the newest OLA staff member, Ms. Nancy Caliman, who is now the DCLG Liaison.

Conflict of Interest. Ms. LeStage reviewed the rules governing confidentiality and conflict of interest, and Ms. Elaine Lee determined that a quorum was present.

II. FUTURE OF THE DCLG

Ms. Kathy Giusti reported on the progress of the Future of the DCLG Working Group, which was formed as a result of the DCLG's discussion with Dr. Andrew von Eschenbach, Director of the NCI, at the DCLG's April 24, 2002, meeting. The working group is examining the DCLG's mission, goals, structure, and future directions.

The working group interviewed several members of the advocacy community and NCI leadership, and learned that:

- The advocacy community has little awareness of the DCLG and its leaders do not perceive the DCLG as their voice to the NCI, although they would like to work with the DCLG. The leaders suggested that the DCLG involve their groups and think broadly across all cancers. They identified clinical trials, survivorship, and research as potential priority areas.
- NCI leadership is familiar with the DCLG, but is less aware of the DCLG's impact. NCI leaders emphasized the need for DCLG members to be ready to work with them without additional training, and to focus across all cancers. NCI leaders identified clinical trials, survivorship, and research priorities as potential areas of focus for the DCLG.

The working group concluded that the DCLG mission is appropriate but the group is not fully achieving that mission, particularly in making recommendations to the Director and serving as a conduit between the advocacy community and the NCI. The DCLG suggested to Dr. von Eschenbach that the group needs to be involved in strategic planning at NCI to understand the Institute's issues and become stronger spokespersons for these issues. The NCI should obtain tactical advice on NCI plans and programs from members of the Consumer Advocates in Research and Related Activities (CARRA), not the DCLG.

On September 12, 2002, the working group recommended to Dr. von Eschenbach that the DCLG:

- Conduct a quantitative survey of the advocacy community to assess its perceptions of the NCI and the DCLG, and its priority areas. The survey will establish a baseline against which the DCLG's progress can be measured every year.
- Enhance the NCI's database of advocacy organizations by collecting information on the organizations, including contacts and key areas of focus and potential outreach, through the quantitative survey.
- Develop a process for ongoing communication with the advocacy community.

The working group proposed that the DCLG identify NCI priority areas that are supported by both the advocacy community and NCI leadership. Future DCLG candidates will need expertise in these priority areas and should represent diverse points along the cancer continuum. Support from the NCI Director will be needed in the form of communications, budget/resources, and training.

Dr. von Eschenbach has approved the conduct of a quantitative survey for the DCLG and the working group has developed an outline of the survey, solicited bids, and selected a contractor. The working group expects that the survey will be fielded in mid-March and a final report will be prepared in mid-May. The working group will then request feedback on the advocacy community's priorities from Dr. von Eschenbach and the NCI leadership before recommending future priorities for the DCLG.

Discussion. Ms. Susan Butler suggested that the results of the survey be communicated back to the advocacy community to enhance relationships. She finds that advocacy groups want direct access to the NCI leadership without going through the DCLG. Ms. Giusti replied that larger advocacy groups have access to Dr. von Eschenbach, but many smaller groups need help from the DCLG to understand the NCI's perspective on certain issues.

Mr. Henry Porterfield pointed out that many survivors are not affiliated with any advocacy group and their input is important.

Ms. Giusti explained that the survey would probably be distributed by e-mail. Ms. Vernal Branch suggested that the survey also be available on the Web and through Internet message boards to reach smaller organizations.

Ms. LeStage thanked Ms. Giusti and the Future of the DCLG Working Group for their hard work and expertise.

III. DISCUSSION OF THE DCLG'S FUTURE ROLE—STRATEGIC, OPERATIONAL, OR BOTH

Dr. von Eschenbach emphasized the importance of keeping an open mind about the DCLG's future, but the DCLG is needed to speak to broader issues concerning the needs of cancer patients and the community, although some groups will always want to speak directly with the

NCI about their agendas. Dr. von Eschenbach stressed that a time line cannot be established for the DCLG's assuming this role, as this will require an iterative process. Dr. von Eschenbach's commitment to the DCLG is to continue to define a very specific, unique, value-added role and opportunity for the DCLG while the DCLG continues to determine how that role can best serve the larger community.

Dr. von Eschenbach seeks input from all of the NCI's advisory boards, including the DCLG, on ends, not means (which are operational issues). The NCI has created a more effective team leadership process over the past year to do the strategic planning needed to define its ends, and is viewing its portfolio in terms of the discovery, development, and delivery continuum needed to fulfill the NCI's purpose of eliminating the suffering and death due to cancer. An example of an ends decision is whether the NCI should consider the long-range development of more platforms for delivery of state-of-the-art cancer care and how these should be integrated into the community to ensure that every patient is receiving access to this care. Dr. von Eschenbach welcomed the DCLG's broad perspective on such issues.

Although the NCI has an annual budget, it is beginning to examine its investments over longer periods of time. For example, the NCI may need to invest more in certain long-term projects up front before shifting those additional funds to other projects, which will require changes in the NCI culture. The NCI would like advice about this process from the DCLG.

Dr. von Eschenbach is committed to requiring the use of CARRA members whenever the NCI needs input from the advocacy community, unless sufficient written justification to the contrary is provided.

Discussion. Ms. Giusti asked about the time line for defining the DCLG's role but Dr. von Eschenbach does not believe that this question can be answered at this time because gaining the confidence and trust of the advocacy community will not happen overnight. Mr. Doug Ulman emphasized the importance for DCLG members of putting aside their organizational roles and assuming a broader view, as this will be crucial to engage other advocacy organizations.

Dr. Marisa Weiss suggested that many ends at the NCI, such as the "Five a Day" effort, would benefit from the advocacy community's input. The DCLG is an important channel to the advocacy community for NCI information. Dr. von Eschenbach is focusing on ends relating to input to, rather than from, the NCI. No barriers exist to the DCLG's continuing to serve as an effective conduit for the dissemination of programs like "Five a Day," but the DCLG needs to determine how to do so. Ms. Giusti pointed out that the DCLG's survey would collect information on whom to contact about such issues. Mr. Ulman suggested that while the DCLG builds its database and plans its survey, its members should discuss the DCLG whenever they go to meetings. In this way, DCLG members can start building relationships with the advocacy community immediately.

Ms. Butler asked Dr. von Eschenbach to identify some of the DCLG's accomplishments, and Dr. von Eschenbach pointed to the formation of CARRA, which has proven a very valuable addition to the NCI. Ms. LeStage noted that in the past the DCLG was more involved in operational tasks

but now that CARRA is available, its members can take on these roles, allowing DCLG members to step back from that type of involvement and find ways to be more strategic.

IV. COMPOSITION OF THE DCLG IN THE FUTURE

Ms. LeStage explained that the interviews conducted by the Future of the DCLG Working Group revealed a need for broad representation on the DCLG. The DCLG may need to consider adding more leaders who are experienced and well known at the national level. However, this might diminish the DCLG's grassroots representation and such organizations may have the greatest need to communicate their concerns to the NCI through the DCLG.

In the past, DCLG recruitment has been very lengthy and expensive. Ms. LeStage asked DCLG members to consider the kinds of members needed for the DCLG and how to select them.

Dr. von Eschenbach suggested two criteria for DCLG membership:

- The DCLG needs to be a team of members whose areas of expertise, when combined, produce the synergy needed to represent the broad cancer community.
- DCLG members must not represent any specific agenda or tumor, but rather the problem of cancer as it affects this Nation.

Mr. Chris Pablo suggested that the DCLG focus on representing organizations that cannot independently exert influence on the NCI or Congress. Ms. Love pointed out that many grassroots representatives are strong leaders. If DCLG members need familiarity with the processes and workings of the NCI, this might exclude grassroots members who may know little about the NCI. But Dr. von Eschenbach believes that if DCLG members are to focus on ends, they do not need a high level of familiarity with the NCI. Ms. Giusti suggested that new DCLG members become familiar with the NCI by studying its Web site and talking to its leadership.

Mr. Ulman suggested that allowing advocacy organizations to elect DCLG members would give advocacy groups an immediate channel of communication. Dr. von Eschenbach is open to discussing such an election process, but Ms. Love argued against an election process because this might result in the selection of the most well known leaders of the largest organizations. The current process works well and the only concern appears to be the need for more qualified candidates. Ms. Giusti suggested that the DCLG consider this issue at a future meeting.

V. INPUT FROM THE PUBLIC

Mr. Greg Bielawski, a CARRA member, suggested that the approximately 200 CARRA members could become a source of trained, qualified DCLG candidates. Ms. Giusti agreed that with their training and experience, CARRA members might be very appropriate DCLG candidates. Mr. Bielawski expressed the frustration felt by many CARRA members who have not yet been used for NCI activities. Ms. Giusti replied that the DCLG is working to address these concerns.

Ms. Judy Jones, a CARRA member, does not support election of the DCLG members by advocacy groups. Instead, DCLG members should identify the kinds of people needed to fill gaps in the group's membership and select the right mix of DCLG members.

Ms. Marlene Oliver, a CARRA member, e-mailed the following message to the DCLG:

> "In Europe, physicians are now being discouraged from prescribing chemotherapy. In their hands, chemotherapy is effective (= "cure") in only 10-20 percent of patients. The trend in research should be toward the NCI discouraging further stand-alone chemotherapy trials. The NCI should encourage cancer-cell targeted trials, with synergistic chemotherapy, where appropriate or without chemotherapy at all.
>
> For example, many formerly fatal or nearly always fatal cancers are being successfully targeted abroad much more widely than in the United States. For liver, pancreatic, metastatic, bone, hematologic, brain (glioblastoma multiforme) and neuroendocrine cancers, medical isotopes, which may be enclosed in microspheres that are injected, or are bound to peptides (portions of proteins) specific to the cancer given via IV therapy in a 10 to 20 minute treatment. As the isotopes' short-lived, short-acting radiation decays, the cancer is "zapped." This leads to at least 70 percent of patients responding, even after other treatments failed. If anyone is interested, there are "before" and "after" scans that illustrate the efficacy of these therapies in both children and adults.
>
> Cost savings to the Medicare/Medicaid program, if these isotopes were available in sufficient quantity and quality and variety, is projected to be in the tens of billions of dollars annually. Isotope shortages have been identified by NCI researchers."

VI. DIRECTOR'S REPORT

According to Dr. von Eschenbach, the ultimate reason for the existence of the NCI is to eliminate the suffering and death due to cancer. The NCI must therefore define the programs, opportunities, and interventions needed to bring about this goal. The NCI plans to accomplish this by learning about this disease from the point of view of the cancer cell, the person with cancer, and the populations affected by cancer. Based on this understanding, the NCI will develop interventions that will be delivered to all who are in need.

Some aspects of the ultimate solution to eliminating the suffering and death from cancer can be accomplished only by the NCI, but the NCI cannot complete a substantial portion of these tasks alone. The NCI therefore needs to foster strategic partnerships.

The NCI is in a uniquely exciting time because a profound change—the revolution in biomedical research—can propel the organization into almost exponential growth. For the first time, scientists are beginning to truly understand the genetic, cellular, and molecular mechanisms that govern how cancer develops and behaves, and this understanding can lead to the development of mechanistically based interventions as opposed to the old "seek and destroy" mechanisms. The new mechanistic view of cancer applies not only to the cancer cell but also to how the cancer cell and the person interact, which is opening up new vistas for approaching the person with cancer.

The new developmental agenda demonstrates the importance of developing new public-private partnerships and enhancing the Institute's partnerships with other Federal agencies. The NCI is working even more closely with the U.S. Food and Drug Administration (FDA) through the efforts of its new director, Dr. Mark B. McClellan. Drs. von Eschenbach and McClellan are committed to bringing the two agencies together to accelerate the development of new interventions, the process of approval, and the ability to provide these new interventions to the community where they are most needed.

The NCI has also created a new organizational structure that complements this functional paradigm. Dr. Anna Barker recently joined the NCI as the Deputy Director for Strategic Scientific Initiatives and is helping to facilitate and accelerate the transition from discovery to development. The NCI is now seeking someone to facilitate the development-to-delivery part of the agenda and is considering how to facilitate the integration of the cancer centers so that they can work more effectively as networks for the delivery of state-of-the-art care. The next step is integrating the cancer centers more effectively with the clinical trials infrastructure, and then embedding these into the community in a more effective way.

Dr. von Eschenbach would like the DCLG to help the NCI meet its leadership responsibility to deliver on the promise created by the new scientific knowledge by creating interventions that are delivered to all who need them. The DCLG's knowledge of the community and its needs could be extremely important in informing the NCI as it conducts its planning.

The NCI does not yet have a 2003 budget and continues to work under a continuing resolution. The Senate recommended a 2003 budget for the NCI of $4.6 billion, which is essentially the same as the President's budget. If the NCI receives the recommended budget, it will continue to support its non-competing research program grants with a 3 percent increase, but fewer resources will be available for competing applications and renewals. However, Dr. von Eschenbach emphasized that the NCI has received more applications and awarded more grants in recent years.

Discussion. In the experience of Ms. Giusti, the greatest concern to advocacy groups is getting drugs to the market as rapidly as possible. She agreed with Dr. von Eschenbach that partnerships will be needed to make this happen and the more the DCLG knows about this process, the more its members can help the NCI. Dr. von Eschenbach suggested that as the CARRA members become more involved in NCI activities, this will help with dissemination, and strongly encouraged as much networking as possible.

Ms. Branch suggested that CARRA members provide input on informed consent and clinical trials for Specialized Programs of Research Excellence (SPOREs) in their local areas. Ms. Handley noted that NCI staff members are helping make this happen.

VII. NIH COUNCIL OF PUBLIC REPRESENTATIVES (COPR) STRATEGIC PLANNING

Ms. Nancye Webb Buelow and Ms. Debra Lappin, J.D., are members of the NIH Council of Public Representatives (COPR), which, like the DCLG, facilitates interactions between the NIH

and the general public. Ms. Buelow explained that the COPR was formed in 1998 to improve priority setting and public input at the NIH in response to a recommendation from the Institute of Medicine (IOM). Today, the COPR brings the public perspective to NIH Director Dr. Elias Zerhouni and helps the public understand what the NIH does and how it sets its research priorities. COPR members also participate in tasks that address the goals and concerns of the NIH and COPR. Ms. Lappin added that the COPR brings a critical voice to the new discussion about public accountability for the NIH.

The COPR has up to 21 members appointed by the NIH Director, who serves as the group's chair. The members serve for overlapping 3-year terms and include patients, family members of patients, healthcare professionals, scientists, health and science communicators, academics, public servants, and health- and science-related professionals.

Ms. Lappin compared the COPR and the DCLG. Both groups are official Federal Advisory Committees; consist of members of the public; and do their work through regular meetings, work groups, and conference calls. But the groups differ in that the COPR looks across the NIH and diseases, while the DCLG focuses on the NCI and cancer. The COPR is located in the office of the Director, who serves as the group's chair, while the DCLG chair is a member of the group.

COPR members have participated in:

- Internal oversight committee for gene transfer research at NIH,
- NIH committee focused on health disparities,
- NIH budget retreat,
- Review of the NIH Government and Performance Results Act,
- Review panels for Institute Directors,
- Reduction of regulatory burdens panels,
- Office of Medical Application Research discussion group,
- National Library of Medicine (NLM) PubMed Central Advisory Committee,
- Talks to groups across the country (including the DCLG and other advisory groups), and
- Site visits to increase public awareness of the NIH.

The COPR has engaged in a strategic planning process with the help of a facilitator. As part of this process, council members brainstormed areas of interest to the NIH and the public and identified successes and areas for improvement. The COPR then developed an initial list of priorities that it is currently assessing.

This discussion with the DCLG is part of the COPR's effort to enhance communication across the NIH with other groups and advisory bodies. As part of this effort, the council is exploring the possibility of holding a summit with other public groups and advisory bodies across the NIH to address how public input should be obtained from and used at the NIH.

Ms. Lappin introduced Ms. Jennifer Gorman Vetter, COPR Coordinator and Public Liaison Officer for the NIH, and invited the DCLG to visit the COPR's Web site at http://copr.nih.gov.

Discussion. Ms. Love asked about other advisory groups like the DCLG at other Institutes. Ms. Lappin replied that the DCLG is the only advisory group of its kind at an NIH Institute, but

every Institute advisory council has public members and several Institutes are beginning to include a public member in all study sections.

Mr. Porterfield asked about the COPR's role at the NIH budget retreat. Ms. Lappin explained that the budget retreat brings all of the Institute Directors together to review the NIH budget and strategic directions, but these events focus more on strategic planning than allocation of funds.

Ms. Giusti inquired about the COPR's report on human research protections in clinical trials. Ms. Lappin explained that a working group developed this report with support from a writer and counsel from the Office of the Director of Extramural Research. The COPR presented the report at a public meeting and it is available on the council's Web site.

Ms. Buelow explained that COPR members are selected in the same way as DCLG members. Ms. Gorman Vetter added that information on the applications process is available on the COPR Web site. The COPR typically receives 100 applications for the 6-9 slots it fills every year. In addition to soliciting applications through the COPR Web site, notices are sent to professional and advocacy organizations with a broad range of interests. Ms. Gorman Vetter also asks the 27 public liaison officers at each of the NIH Institutes to publicize the application process to their constituencies. Ms. Handley pointed out that OLA does similar promotion for the DCLG and that CARRA will provide a wonderful outlet for dissemination.

Ms. Gorman Vetter explained that a panel appointed by the NIH Director reviews the COPR applications and the NIH Director ultimately selects the new members. Scoring and evaluating the applications is extremely time and resource intensive, as three independent evaluators review every application. Ms. Lappin added that COPR members do not regard themselves as representing particular constituent groups, although they are involved with many such groups.

Ms. Butler asked the COPR representatives to comment on what the council has done well and what it has done less well. Ms. Lappin believes that the COPR did a good job on its research protections effort, but it still needs to determine how to have appropriate and meaningful dialog around the establishment of scientific priorities. Ms. Buelow suggested that DCLG read the COPR's paper on research protections, available at http://copr.nih.gov, and provide feedback.

Ms. LeStage pointed out that the COPR has 21 members with 3-year terms and is chaired by the NIH Director, while the DCLG has 15 members, is moving to 4-year terms, and is chaired by a member. She asked if 21 members is a good number, and what the impact is of having the NIH Director serve as chair. Ms. Buelow believes that 15 is a good number, although the COPR's 21 members work well. She also supported the 4-year term because it takes so long to become comfortable with this role. Ms. Lappin added that the COPR has considered having an internal chair, but the time with Dr. Zerhouni is very valuable and enhances the council's relationship with him.

Ms. Branch suggested that the COPR and DCLG explore opportunities for collaboration because both groups are interested in some of the same issues, such as health disparities and clinical trials. Ms. Lappin agreed.

Ms. Handley pointed out that, just as COPR members serve on other NIH committees, DCLG members serve on several NCI standing committees. Although this work may be less visible than such accomplishments as the CARRA program, it has affected how NCI staff do their work and the outcomes of that work. Ms. Love noted that the DCLG has worked successfully with champions within the NCI to obtain positions at the table for advocates, not just DCLG members, in several initiatives at the NCI. Ms. Lappin noted that having the Institutes be more open to using advocates is one of COPR's three focus areas. Perhaps every Institute that is larger than $750 million should have an advisory body like the DCLG.

Ms. Gorman Vetter's office has developed a model presentation on disk that is updated every year. Some members use this "NIH 101" presentation when they speak before public groups, advisory committees, and others. Other tools and resources are in development.

Ms. Lappin urged the DCLG to respond to the public's demand for a new kind accountability for its investment in research. Groups like the COPR and the DCLG can do this before it is mandated by Congress. Ms. Lappin suggested starting by identifying the Institute's mission, and determining whether the Institute is meeting that mission and how the DCLG can help the Director hold himself accountable for meeting the Institute's mission.

Ms. Gorman Vetter recommended that DCLG members read the public liaison bulletin available at http://forthepublic.nih.gov. This quarterly bulletin lists outreach activities and resources at all of the NIH Institutes that are of interest to the public. When the NIH selected the first 20 COPR members, it began sending the other 280 applicants this bulletin, COPR meeting minutes, and other information and soliciting public comment from this group when needed.

VIII. PUBLIC-PRIVATE PARTNERSHIPS

Dr. Anna Barker noted that she has always been a great proponent for the role of cancer survivors and advocates in all aspects of cancer research. The survivor and advocate community has provided the science community with a great deal of the information needed to craft, direct, and implement its programs.

As the population ages, Dr. Barker predicts an increase of 25-30 percent in cancer incidence and mortality worldwide. The situation will be almost cataclysmic in 10-15 years unless unprecedented partnerships are formed. Knowledge has doubled in the past 10 years and is likely to double every 5 years, especially in genomics and proteomics, and new possibilities exist for breakthroughs in genomics and proteomics that will dwarf all breakthroughs to date. The NCI plans to facilitate and accelerate the progress of knowledge and technology transfer through more effective multi-sector partnerships. The DCLG is a big part of this and Dr. Barker would like this role to be even larger.

Discovery will have no impact unless someone is willing to commercialize the results, but cancer is not a popular market because its many targets generally result in small markets. The way in which drugs are reviewed makes commercialization even more difficult.

Dr. Barker described several NCI programs of which DCLG members should be aware, so that they can determine where they can best make a contribution. These programs include:

- Innovative Molecular Analysis Technologies (IMAT), which identifies and measures molecular signatures and technologies. IMAT has produced 10 patents, 13 licenses to commercialize technology, 4 new companies, and 33 partnerships.
- Unconventional Innovations Program (UIP) has produced 5 licenses, 11 patent applications, 1 new company, and 11 partnerships.
- Cancer Genome Anatomy Project (CGAP) is building knowledge platforms through large community-based programs.

As the NCI progresses in genomics and proteomics, more large programs will be required, such as a program resembling the Human Genome Project, to develop a picture of the normal human proteome. But one of the most important tasks for the NCI in the next 5 years is to the capture all of the information it is generating through databases and systems that are accessible to all. Dr. Barker suggested that the DCLG invite Dr. Ken Buetow to speak to the DCLG about the remarkable set of knowledge platforms he is building. Dr. Barker also suggested that the DCLG learn more about how to transfer technology and how to facilitate this translation because integrating and transferring the knowledge technology that results from the projects listed by Dr. Barker will require scientific investigators who are willing and able to build this platform with developers, clinicians, survivors, and the NCI.

The number of new drug applications to the FDA for all conditions, including cancer, has decreased dramatically in recent years. One barrier to new drug development is the unpredictability of the process for cancer because of the kinds of trials required with survival as the end point. The NCI needs to develop a new target and control paradigm that is proactive, has little or no toxicity, and yields a high quality of life to replace the old search and destroy paradigm that is reactive, toxic, and results in poor quality of life. Another barrier is the expense associated with genomics and proteomics, and the NCI must help reduce the associated risks.

Clinical trials for prevention are even more complex and expensive than for treatment, as they require:

- Annotated tissues from normal and cancer patients. This problem must be solved before others can be addressed. Most of the 207 million tissues in this country were collected badly, and the advocacy community has a key role to play in promoting this issue.
- Surrogate end points for cancer trials that reflect the nature of the disease. Intermediate end points would reduce the duration and expense of trials.
- A national, integrated strategy for developing drugs, especially genomic- and proteomic-based drugs, in the future.

Dr. Barker believes that this is an appropriate focus area for the DCLG.

To engage the private sector, the NCI must determine how to establish cancer as a broader market, which probably means identifying common disease mechanisms across cancers. To some extent, this is already occurring with cyclooxygenase 2 (COX2) inhibitors that are very good chemopreventives for colon cancer. The NCI can also do much to reduce the risk of

investment by finding ways to treat cancers as orphan diseases and lower the barriers of target validation for new therapeutics.

Dr. Barker discussed several current projects in which NCI is providing leadership to address key barriers in areas such as drug discovery; and also presented some ideas for future integrative initiatives that NCI could undertake to facilitate progress, including:

- Cancer Therapeutics/Preventives, pre-competitive demonstration programs;
- Development of a National Tissue Resource (ongoing through the National Dialogue on Cancer (NDC)) (the DCLG is welcome to join this effort);
- A collaborative effort on surrogate end points (ongoing through the NDC) (Dr. Barker is the NCI liaison to the FDA);
- Improving regulatory review of cancer agents and technologies (the DCLG might wish to play a role here);
- A systems biology paradigm that will include therapeutics (future initiative);
- The development of nanotechnology, which allows *in vivo* monitoring in real time to detect cancer very early and deliver payloads to specific cells (future program); and
- The Integrated Advanced Biomedical Research and Biotechnology Center at Frederick (in concept development).

Dr. Barker recommended that the NCI should take a more proactive role in facilitating the development of responsive public-private partnerships for technology transfer and development as follows:

- Continue to support the best basic science in the world and fund more innovative research and technology development;
- Bring key players together to solve the problems of clinical research, surrogate end points, and tissue access;
- Support cutting-edge, pre-competitive initiatives that push the forefront of science but are accessible to everyone;
- Design and implement mutually beneficial partnerships;
- Develop an unprecedented partnership with the FDA; and
- Provide training, especially in development and technology transfer. Clinicians are needed who have one foot in basic science and the other in the clinical world to do technology transfer.

Discussion. Ms. Branch asked how the NCI identifies potential public or private partners. Dr. Barker replied that the NCI begins by identifying areas with the largest gaps and the greatest promise. The Institute then identifies companies and agencies that might be interested in these areas.

Mr. Porterfield asked Dr. Barker to suggest high-priority areas in which the DCLG might become involved. Dr. Barker identified tissue access as the most significant of these issues, especially since some members of the advocacy community do not regard this issue in a positive light. The greatest hurdle to building a new system will be buy-in from the survivor community, which will require an approach to informed consent that preserves genetic privacy. Ms. LeStage requested clarification on how the DCLG can best contribute to tissue access, without duplicating the efforts of others. Dr. Barker replied that the advocacy community needs to

provide a set of guidelines for tissue access and no other group is likely to do this. Tissue access needs to become an acceptable national initiative.

Dr. Weiss suggested that the DCLG learn what types of tissue are needed and encourage patients to request that such tissues be collected. Dr. Barker replied that fresh frozen tissues are needed. One challenge is the role of pathologists in tissue collection in the context of the difficulties currently faced by the pathology profession. The NCI needs to determine how best to work with this community.

Dr. Weiss emphasized the need for a genomics and proteomics nomenclature that is useful to patients. Dr. Barker agreed that the jargon, which will only get worse, is a problem. A patient-friendly thesaurus would be helpful. The National Cancer Advisory Board's (NCAB's) bioinformatics committee is developing a common language for scientists, and perhaps a subcommittee could produce a thesaurus for the lay public. Dr. Barker suggested that this recommendation could come from the DCLG, which should invite Ken Buetow to discuss this.

Ms. Branch served on the tissue committee of a SPORE in the San Francisco area that developed educational materials, sent a recruitment letter to women with breast cancer, and helped develop an understandable informed consent form. As a result, the committee recruited more volunteers than anticipated. Dr. Barker supports community-based activities like this one, as the NCI does not always know what approaches are most appropriate for a given community.

IX. REPORT FROM THE OFFICE OF CANCER SURVIVORSHIP

Dr. Julia Rowland provided an update on what she considers one of the most exciting of recent activities in the Office of Cancer Survivorship—the new Cancer Survivorship Extraordinary Opportunity. The reasons why this issue has come to the fore include:

- The population of survivors has increased, with at least 8.9 million cancer survivors in the United States today.
- The vast majority of cancer survivors today will live a long time with their diseases, so cancer has become a chronic illness for many.
- More than 80 percent of all cancer patients are treated in the community, rather than in large comprehensive centers, raising the challenge of how to reach them and ensure that quality care is delivered in all of those settings.
- Three out of every four American families will have at least one family member diagnosed with cancer.
- Cancer has physical/medical, psychological, social, and existential/spiritual effects.

The IOM has issued reports on quality cancer care and palliative care, and is now developing two reports on survivorship. In addition, all of the Progress Review Groups (PRGs) have included survivors, so all of the PRG reports address survivorship concerns. The Survivorship Extraordinary Opportunity will leverage the information being collected by several new NCI activities and resources as well as the efforts of a small but growing cadre of researchers.

The overall goal of the Survivorship Extraordinary Opportunity is to reduce the adverse effects of cancer diagnosis and optimize the outcomes for cancer survivors and their families. The

Extraordinary Opportunity includes six objectives, and Dr. Rowland highlighted the following objective as particularly important to the DCLG:

- Enhance the development and dissemination of new interventions and best practices, in collaboration with other Federal and health- or cancer-related professional and nonprofit organizations.

The NCI's first response to the Survivorship Extraordinary Opportunity was to reissue the long-term cancer survivors request for applications (RFA). The previous survivorship RFA, issued in 1997, resulted in 16 funded grants. Dr. Rowland summarized the findings from this initial group of research projects, which have resulted in the identification of several interventions. The reissued RFA will build on the science generated in the first round and provide an additional stimulus to the research community to study survivors 5 years or more after diagnosis. Researchers will focus on specific survivor groups and underserved populations, develop and test interventions for those living with late and persistent physiologic or psychosocial effects, and promote tool development and sharing. These projects will build on existing cohorts and databases and promote collaborations to develop a cadre of investigators.

Other cancer survivorship initiatives in FY 2003 include:

- A needs survey on the information across the treatment trajectory needed by patients undergoing radiation and chemotherapy,
- A survivors information needs literature review,
- The second meeting of the long-term pediatric survivors group, and
- An Extraordinary Opportunity Steering Committee to discuss how the program's goals will be achieved.

The Senate has now addressed cancer survivorship specifically in the Departments of Labor, Health and Human Services, and Education and the Related Agencies Appropriations Bill of 2003. The Senate supports an aggressive expansion of the NCI's activities in this area and a report by April 1, 2003, outlining these activities. Although the Senate recommended a consensus conference, the NCI will probably focus instead on its Biennial Cancer Survivorship Conference, cosponsored with the American Cancer Society, which was held for the first time in June 2002.

Discussion. Dr. Rowland explained that the NCI intends to collaborate with a range of partners, including the private sector, to enhance the development and dissemination of new interventions and best practices. The NCI wants to avoid duplication, so it plans to develop collaborations and build on what has already been developed.

Mr. Ulman wondered if the survivorship field has enough investigators. Dr. Rowland replied that there are never enough investigators. The original survivorship RFA included R03 mechanisms for junior investigators, as these grants are easier to obtain. Some investigators from other fields, such as pain, aging, and caregiving, are now applying their expertise to cancer as a result of the NCI's new initiatives. The NCI is also trying to make it possible for investigators to build a career in survivorship through training grants and junior investigator grants that provide the experience needed to obtain R01 grants.

Dr. Weiss pointed to the need for mentorship of junior investigators, as many are discouraged by the difficulty of obtaining grants. Dr. Rowland noted that the NCI's program staff work hard to help junior investigators succeed in their applications by targeting them more appropriately. When investigators respond to this type of advice and resubmit their applications, their chances of obtaining funding increase significantly.

Mr. Ulman pointed out that senior investigators are now seeking $50,000 grants from the Lance Armstrong Foundation, which tells them that they should apply for R01 grants. But funding is so difficult to obtain that investigators seek whatever is available. Dr. Rowland noted that the language for the R03 mechanism does not specify that only junior investigators can apply, as the awards are open to senior investigators from other fields who want to become familiar with the cancer area. But senior investigators in cancer should apply only for R01 awards.

Survivorship Knowledge Exchange Team. Mr. Ulman announced the formation of the Survivorship Knowledge Exchange Team in Dr. Rowland's office. The team has DCLG representation. Dr. Rowland explained that the knowledge exchange teams are cross-disciplinary groups designed to disseminate the results of research, including interventions, in specific areas. The Survivorship Knowledge Exchange Team is attempting to make all of the research data, publications, and materials that have been evaluated accessible to the broader population, including the research and consumer communities. Dr. Rowland expects to complete a time line for the team's tasks by the end of this month.

Ms. Handley added that the Division of Cancer Control and Population Studies is building a Web site, Cancer Control Planet, to house evidence-based interventions and products. This Web site is a collaboration among the NCI, the American Cancer Society, and the Centers for Disease Control and Prevention (CDC). Dr. Rowland noted that the knowledge transfer teams would inform this project.

Ms. Karen Packer hopes that the knowledge exchange team will consider finding ways to communicate with physicians who care for patients in the community, particularly in rural areas. Dr. Rowland asked DCLG members to share any ideas they have on this subject with her.

Ms. Love reported that the CDC, which funds most state cancer control plans, is beginning to focus on survivorship. Most state cancer control plans are administered through departments of health and are very heavily focused on screening, tobacco control, and prevention. Ms. Love has seen resistance from other state representatives to addressing survivorship and they could use some help, perhaps from the Survivorship Knowledge Exchange Team. Sharing the information on survivorship statistics and issues might help states incorporate survivorship into their cancer control plans.

Mr. Ulman announced that the Lance Armstrong Foundation has convened a working group to see what can be done from a public health perspective using what will soon be known about survivorship. DCLG members will be invited to a meeting this summer to develop a national public health plan on survivorship so that states can select from many interventions that work.

Dr. Rowland pointed out that the challenge in developing a survivorship plan is immense because the field is immense. There is no consensus on follow-up for individual cancer survivors, as this depends on the type of cancer, premorbid conditions, and treatments to which the individual was exposed. But some specific recommendations may be available.

Dr. Rowland noted that the information she presented in her slides is public information and DCLG members should feel free to use these data in their own advocacy or professional activities. Ms. Lee will e-mail the slides to all DCLG members. The prevalence data and all of the Office of Cancer Survivorship reports are available on the Web at http://survivorship.cancer.gov.

X. RECESS

The meeting recessed at 4:39 p.m. on January 6, 2003.

January 7, 2003

Ms. LeStage called the meeting to order at 8:05 a.m. on January 7, 2003.

XI. WELCOME AND OPENING REMARKS

Ms. LeStage welcomed participants to the second day of the DCLG's 22nd meeting. She also welcomed DCLG member Mr. Michael Katz, who had not attended the meeting on January 6.

XII. ETHICS REPORT

Ms. Cynthia Morgan reviewed the ethics rules that pertain to DCLG members as Special Government Employees. Ms. Morgan reminded DCLG members that they are required to submit financial disclosure forms prior to their appointment to the DCLG, and to update that information prior to each meeting. Ms. Morgan also reminded DCLG members that:

- They may not accept anything of value in return for performing their official duties.
- They may not be compensated, except by the government, for any speaking, teaching, or writing that relates to their official DCLG duties.
- Although they are not restricted from charitable fundraising in their personal capacities, they should not use their DCLG membership for this purpose.
- They must receive prior authorization to serve as expert witnesses in matters that they have addressed as members of the DCLG.
- They may not use or appear to use their public office for private gain.
- They may not be compensated by any foreign government. If a DCLG member is offered compensation for travel or an honorarium for a talk at a foreign university, they should inform Ms. Morgan's office in advance to determine whether the institution is public or private.
- They are prohibited from engaging directly or indirectly in lobbying members of Congress. DCLG members who want to contact Congress should first speak to Ms. Lee.
- They may not use their DCLG affiliation when engaging in political activities.

XIII. CONSUMER ADVOCATES IN RESEARCH AND RELATED ACTIVITIES (CARRA) UPDATE

Ms. Brooke Hamilton, the CARRA program coordinator, reported on the activities of CARRA over the past year. Ms. Hamilton invited DCLG members to call or e-mail her at any time about the CARRA program, as their suggestions and comments are very valuable.

Ms. Hamilton announced that the CARRA program has been up and running for slightly more than a year, thanks in large part to the efforts of many individuals, including DCLG members. During the program's first year, it received 101 requests for CARRA member involvement, which represents a substantial increase in advocate participation. The Division of Extramural Activities is the source of more than half of all requests for CARRA participation, and the Office of the Director generates approximately one-third of all requests. Once the program is fully staffed, it will better anticipate the number of requests and improve customer service.

Ms. Hamilton shared some feedback from CARRA members. Those who have participated in an NCI activity are generally eager to participate again. Those who have not participated appreciate receiving information from the CARRA program, but are often frustrated over their lack of participation. OLA responds to their concerns as they arise.

CARRA now has three planning groups:

- CARRA Planning Group,
- CARRA Evaluation Planning Group, and
- CARRA Training Planning Group.

The Evaluation Planning Group—which includes CARRA members, a DCLG member, OLA staff, and other NCI staff members—is helping create a proactive, rather than reactive, evaluation process. The NCI has now signed a contract with Westat, which will help develop and implement the CARRA evaluation. Once the evaluation plan that is currently under development is complete at the end of January, the contractor will begin implementing the plan.

Discussion. Ms. Giusti asked about the impact of Dr. von Eschenbach's announcement that NCI staff must use CARRA members (unless they document their reasons for doing otherwise) on planning for CARRA, and how this announcement will be communicated throughout the NCI. Ms. Hamilton replied that this new policy might affect the priorities selected for evaluation. For example, as a result of the policy, the evaluation will probably focus less on whether the program increases the use and appreciation of the value of CARRA members by NCI staff and more on roles and responsibilities. Ms. Handley added that now that OLA understands Dr. von Eschenbach's view of CARRA, it needs to examine the implications of this view. A proposal for implementing the policy will probably be taken to the CARRA Planning Group.

Ms. Giusti pointed out that Dr. von Eschenbach cited CARRA as one of the DCLG's successes and the DCLG should build on this success. The stronger the policy is regarding CARRA use by NCI staff, the better the program will do. Ms. Handley noted that OLA needs to develop an exception process and communicate the policy to staff in a way that will respond to their concerns. Ms. Giusti suggested that the message come from one of their peers who uses CARRA

and is willing to share their appreciation of the program. Ms. Handley suggested discussing implementation of the CARRA use policy with the Executive Committee, as Dr. von Eschenbach will be at the meeting. Ms. Handley welcomed suggestions on how to communicate the CARRA use policy to NCI staff.

Mr. Michael Katz suggested concentrating outreach efforts on NCI divisions that use large numbers of non-CARRA advocates. Ms. Hamilton explained that OLA does not have information on these activities, as NCI staff contact these advocates directly without informing OLA.

Ms. Butler believes that the top concern of CARRA members is having the opportunity to participate in NCI activities. Ms. Hamilton explained that CARRA members have not been used more than once unless they have a unique area of expertise. Ms. Butler suggested that OLA share with CARRA members on a regular basis the process used to select individuals to participate in activities.

Ms. Giusti asked if the original 70 CARRA members who were grandfathered into the program are used more often than newer members. Ms. Hamilton replied that OLA does not ask that these individuals be used more often, but NCI staff often request them. Ms. LeStage believes that the program will be more successful now that Dr. von Eschenbach has made his support for CARRA very clear. She suggested that DCLG members express their appreciation to Dr. von Eschenbach for his support of CARRA, as it will make a tremendous difference in the program.

A member suggested that since the terms of the original CARRA members will expire in 2004 and so many have not been used, they be asked to stay on an additional year. Ms. Handley explained that CARRA members can renew for up to two additional terms. OLA will need to determine how many new members the CARRA program needs, and whether it needs more in certain disease areas than others.

Ms. Butler stated that CARRA members with experience in one type of cancer have the expertise needed to work on activities in other types of cancer. She said that experience with a given cancer site is not critical to an advocate's ability to represent consumers at peer review activities.

CARRA Pilot Training. Ms. Nina Ghanem provided an update on plans to provide training on a pilot basis to CARRA members, in response to the needs expressed by NCI staff and CARRA members who have participated in NCI activities. The CARRA Training Planning Group, which includes Ms. Packer, is identifying training needs and objectives.

The planning group sent a needs assessment survey to 28 CARRA members to obtain feedback on the CARRA Planning Group's objectives for the training, most effective learning methods, and best preparation for participation in CARRA activities. Survey responses are due January 15 and about half have already been received. Ms. Ghanem will communicate the results of this survey to the DCLG as soon as they are available.

The planning group plans to review other advocacy training programs, develop a curriculum and time line for the training, and conduct the training.

Discussion. Ms. Giusti noted that CARRA members were asked if they were more interested in scientific or communications issues, and wondered if training will be provided in both areas. Ms. Ghanem replied that those who have requested training have participated in scientific activities. Ms. Ghanem anticipates that the training will be provided to both groups of CARRA members. Ms. Hamilton added that CARRA members who indicate a preference for science or communication activities can still be asked to participate in activities in the area they did not select.

Ms. Giusti asked if a mentorship program is likely to be developed. Ms Ghanem replied that the planning group would consider this possibility. Ms. Hamilton added that mentoring is currently done on an ad hoc basis, as she offers mentors to CARRA members when NCI staff members or the CARRA members themselves request one. Ms. Handley noted that eventually, every time a CARRA member participates in an NCI activity, the CARRA member and the requesting NCI member will complete an evaluation form. The CARRA member will then have the opportunity to evaluate the guidance received from the staff member, which will help OLA with the mentoring process and making program improvements.

Ms. Ruth Lin asked about the dictionary and orientation manual that were developed. Ms. Handley replied that orientation material is available on the CARRA Web site (http://la.cancer.gov/carra), but staff and CARRA members have requested more preparation, particularly face-to-face training.

Mr. Katz has found role-playing to be a very valuable training technique for advocates. OLA might develop a video for CARRA members depicting both appropriate and inappropriate behaviors. Ms. Ghanem replied that OLA is considering a mock peer review activity for CARRA members that might be videotaped and put on the Web for other CARRA members.

Ms. Butler suggested that the training address how to wade through the boxes of applications received prior to participating in peer review. Ms. Ghanem has received requests for this type of training from several CARRA members.

Public Comment. Mr. Bielawski believes that face-to-face training is very important, but this training should not be limited to those who expressed a particular interest in science, as others may have selected communications because they need more training in science. Mr. Porterfield suggested that those who indicate an interest in communication should be asked if they are also interested in science before being invited to receive training.

Mr. Bielawski is training himself in peer review by sitting in on local grant review committee hearings. Other CARRA members might also benefit from identifying ways in which they can enhance their understanding of issues related to CARRA.

Ms. Jones has expertise in communications but recognizes the importance of understanding the science side to grasp the “whole picture.” Those in the communication group may have a particular need for the training because of their limited familiarity with science. Ms. Jones

suggested that some members of the communications group might not be qualified to participate in science training, but Mr. Porterfield believes that anyone who has an interest is qualified.

XIV. UPDATE FROM OFFICE OF SCIENCE PLANNING AND ASSESSMENT AND NEW PROCESS FOR ADVOCACY INPUT INTO THE BYPASS BUDGET

Ms. Kathie Reed announced that Dr. von Eschenbach has made a commitment to seeking broader participation in priority-setting activities and Ms. Reed's group is taking the lead in determining how to accomplish this. Ms. Reed explained that much priority setting at the Institute takes place informally when staff discusses scientific directions, needs, and opportunities and how to increase the capacity of the researcher community to carry out their work. Several informal discussions are also held with stakeholders, researchers, and advocates who can tell the NCI which directions are of interest and needed in the community. The NCI's formal priority-setting activities include the PRGs and the solicitation of suggestions for new extraordinary opportunities for investment.

Dr. von Eschenbach is currently engaging the NCI leadership in a longer-term strategic planning effort that is longer term than the Bypass Budget. NCI leaders are now trying to determine what cancer science could look like in 2015 and what is needed to make this happen. The discovery, development, and delivery continuum is providing a framework for much of this strategic thinking at the Institute – to ensure that research results are translated into useful interventions and that those interventions are delivered to those who can use them.

The NCI receives responses to its draft Bypass Budget every year from approximately 40 organizations, including 6 to 8 advocacy groups and the DCLG. The DCLG's impact is clear in the new Extraordinary Opportunity in Survivorship.

Ms. Reed presented some ways in which the NCI might increase external involvement in Bypass Budget development, including:

- The internal group begins its development process in January or February, and representatives of advisory groups could participate in this initial meeting.
- Ms. Reed's office is working more closely with the planning and budget subcommittee of the NCAB, which is seeking ways to increase participation.
- The draft outline of the Bypass Budget that includes draft milestones in new priority areas could be distributed for comment.
- The NCI could solicit ideas on categories of priorities other than science, such as in public health areas.
- The NCI has working groups and committees that help it plan and implement Extraordinary Opportunities in areas such as tobacco and communications, and similar groups might be needed for each priority area to obtain involvement and input on the details of these plans.
- The NCI is considering town hall-type meetings at professional or advocacy organization gatherings. Video teleconferencing might serve as way to continue these dialogs.

Discussion. Ms. Giusti asked about changes in the Bypass Budget development process. The DCLG's survey of advocacy groups found that many groups do not believe that their views are

included in this document. Ms. Reed replied that the NCI is attempting to change not only the Bypass Budget development process, but the entire range of strategic planning efforts.

Ms. Giusti pointed out that Dr. Barker has a team of 100 people working to identify obstacles in such areas as tissue banking, developing partnerships, and targeted therapies but wondered how these efforts will be funded. Ms. Reed agreed that certain strategic initiatives are needed to make such activities happen. If these initiatives are not specifically called out in the Bypass, it does not mean that they cannot be funded. Often these kinds of activities are components of initiatives of the Bypass Plan.

Mr. Porterfield noted that the NCI has always been open to input from the advocacy community and applauded the move to solicit suggestions before the Bypass Budget is completed, instead of asking for feedback on a plan that has already been developed. The DCLG would like to offer any assistance it can in this process.

Ms. LeStage suggested that the lack of response from outside organizations to the Bypass Budget might be due to the fact that the plan is already virtually complete by the time the groups see it so few changes are possible. She suggested that the NCI solicit comments based on the previous year's Bypass Budget, so that this input is available when the next Bypass Budget is prepared. Ms. LeStage requested a formal presentation to the DCLG on the Bypass Budget earlier in the process so that the group can provide more useful feedback.

Mr. Katz asked how the NCI determines its funding priorities, given that approximately 85 percent of its funds are devoted to ongoing programs. Ms. Reed explained that new funding decisions are made by the NCI Director in consultation with the Executive Committee, Board of Scientific Advisors, and Board of Scientific Counselors. Mr. Porterfield stressed the need for survivors to better understand how funding decisions are made.

Ms. Giusti asked about the response of NCI funding to the changing paradigm of cancer. Ms. LeStage suggested that the only way to make a significant change is to change the types of grants that are funded, and asked who decides which types of grants are funded. Ms. Branch asked if advocates participate in these decisions. Ms. Reed replied that advocates do participate by providing input to the NCI Director on these matters as members of advisory groups and committees like the NCAB, BSA, and BSC.

Ms. LeStage expressed her support for advisory groups for each priority area in the budget. She suggested that advocates also be involved in deciding how the overall "funding pie" is divided, because new advances in science may mean that money should be allocated differently to each piece of the pie. When the DCLG completes its survey of advocacy organizations, it will have a sense of the issues confronting survivors, which will enable the DCLG to provide useful advice to the NCI on how to allocate its funding. Mr. Porterfield added that involving advocates in allocation decisions would help the community feel more involved in the plan. Mr. Katz pointed to the legitimate need for the advocacy community and the public to grasp the NCI's strategy and feel that their money is being well spent.

Ms. Handley noted that this issue has come up in professional society meetings with Dr. von Eschenbach. These groups are also requesting more information about, and input into, decisions about funding priorities. Perhaps the DCLG should invite Mr. John Hartinger and Ms. Cherie Nichols to discuss the strategic planning process for the budget.

Ms. Reed reported that the NCAB planning and budget subcommittee meetings are open to the public. Ms. Reed will share the DCLG's feedback with the NCAB at its meeting on February 11-12, 2003.

Ms. Giusti finds it difficult to be a good spokesperson for the NCI without a better understanding of what the NCI does and why. Ms. LeStage agreed that such an understanding is necessary for the DCLG to provide good input to the NCI, and suggested that Ms. Reed seek input through the DCLG and CARRA listservs.

Ms. Reed asked for input on how to select advocacy organizations to include in the planning process. Mr. Porterfield and Ms. Branch replied that all advocacy organizations should be given the option of participating.

Ms. LeStage proposed inviting Mr. John Hartinger to a future DCLG meeting to help DCLG members understand the NCI's overall budget process, which will help them be better advocates for and have more influence over the Bypass Budget and other parts of the NCI's budget.

XV. QUALITY OF CANCER CARE

Dr. Joseph Lipscomb summarized the activities of the NCI initiative to improve the quality of cancer care. Although the NIH does not usually address quality of care, the continuing disparities between those who do and do not receive high quality care and the lack of understanding about these disparities led to the implementation in 1999 of research initiatives at the NCI to support the improvement of the quality of cancer care. In recent years, this priority has become embodied as a major initiative in the Bypass Budget.

As part of this initiative, the NCI is now developing a core set of end point measures for cancer care in several areas, including health-related quality of life. The Cancer Outcomes Measurement Working Group (COMWG) has 35 experts, including cancer patient and survivor representatives, who are evaluating the state of the science in cancer end point measurement specifically in quality of life. The COMWG's areas of focus are:

- Health-related quality of life, satisfaction/needs, and economic burden;
- Prevention, screening, treatment, survivorship, and end of life; and
- Breast, prostate, lung, and colorectal cancer.

The COMWG hopes that the outcomes data it generates will be used by a wide range of audiences to enhance the understanding of the cancer burden and implications of interventions, inform decisions, and improve quality of care. The COMWG's findings will be published shortly.

In response to a question from Mr. Katz, Dr. Lipscomb explained that Medicare is not required to take health-related quality of life into account in its coverage decisions, although it has the option of doing so. The FDA is wrestling with how take patient-reported outcomes into account and is considering secondary end points for drug approval, as survival is not always an appropriate end point in diverse populations whose survival time frame is often lengthy. The FDA is developing some explicit guidance for researchers who want to use patient-reported outcomes in clinical trials.

Other efforts related to quality of care include:

- The NCI is working with several partners to develop a national cancer data system that is registry based but has links to such information as medical records, surveys, and administrative claims. This will result in a rich longitudinal picture of the kind of care patients receive starting at diagnosis.
- The Cancer Care Outcomes Research Surveillance Consortium (CanCORS) is the largest project in the Bypass Budget. CanCORS is studying the impact of targeted interventions on patient-centered outcomes in lung and colorectal cancer.
- The Quality of Cancer Care Committee (QCCC) is a collaborative effort of several Federal agencies that study, deliver, regulate, or pay for cancer care. Dr. Lipscomb will assume leadership of this committee, whose DCLG representative is Ms. Branch. Several QCCC collaborative projects are now ongoing.
- The National Quality Forum recently convened the Cancer Care Quality Measure Project (CanQual) to bring together private organizations, such as the American Cancer Society and the American Society of Clinical Oncology. CanQual will recommend a core set of measures for consideration and possible adoption by public and private sector organizations. Cancer survivors will probably be involved in some of these activities.

Discussion. In response to a question from Ms. Branch, Dr. Lipscomb explained that the national cancer data system is still in the planning stages. A major goal of the system is to monitor not only quality of care but variations in quality so that they can be understood.

Ms. Packer asked if the results of the efforts described by Dr. Lipscomb would be made public to help patients select providers with good track records. Dr. Lipscomb replied that this is possible, although the NCI's role is to work with others to generate the information that will be used and made available by a range of decision makers in the public and private sectors.

XVI. DCLG NEXT STEPS

Ms. LeStage began the discussion of DCLG next steps with a request for more information about the current status of the advocacy organization survey. Ms. Ghanem explained that OLA and the DCLG have developed the scope of work for the survey and a contractor, ORC Macro, has been selected by OLA and the Future of the DCLG Working Group. Immediately after the current meeting, representatives of OLA and the DCLG were to meet with the contractor to begin planning the implementation of the technical approach. At the DCLG's next meeting, Ms. Ghanem will report more details on the project's time line.

Ms. Giusti explained that the working group has learned that the DCLG sees itself as having a strategic role, while Dr. von Eschenbach views the DCLG as a communications link between the NCI and the advocacy community. Ms. Giusti believes that these two roles are compatible. Ms. Giusti would like to see a time line for determining the DCLG's role, but Dr. von Eschenbach made it clear that such a time line is not currently available. While the DCLG's future is being determined, it needs to maintain the goodwill created through its initial survey of the advocacy community. Dr. Weiss believes that once the DCLG identifies important, compelling tasks, the urgency for establishing the DCLG's role will be clear.

Ms. Butler believes that the DCLG's original purpose is no longer relevant and finding a unique role today is a major challenge. Ms. Handley suggested that the DCLG follow up on Dr. Barker's suggestion that it become involved in the tissue banking issue. Dr. Barker needs input from the advocacy community on this issue soon because she expects some executive order or decision process that will require a response. While the survey process plays out, the DCLG has other opportunities in which to serve a leadership role.

Mr. Porterfield believes that the challenge of the DCLG is to help NCI staff reach the patient community. Although the DCLG represents the patient community, its members know little about how the NCI spends its money. The DCLG is needed to interpret the NCI's programs to the community and bring their thoughts back to the Institute. All of the DCLG members should consider how to better meet this need.

Dr. Weiss suggested that the DCLG follow the COPR's example and select two priorities at this meeting that are important and in which the DCLG can make a difference. The survey is one of these priorities, and Dr. Weiss suggested tissue banking as the other. Ms. LeStage offered to contact Dr. Barker about the DCLG's participation in the tissue banking initiative. Ms. Giusti suggested that CARRA is a third area for the DCLG to address because the DCLG helped develop CARRA and Dr. von Eschenbach has expressed his support for the program.

Ms. LeStage reminded DCLG members that organizational change is always time-consuming and challenging. In the meantime, she is trying to find ways for each DCLG member to participate in the NCI's strategic planning. Ms. Butler suggested that the DCLG members whose terms have been extended assume some of the tasks of DCLG members who feel overburdened.

Ms. Handley explained that OLA helps find opportunities for the DCLG and asked what types of assignments DCLG members would like. The strategic planning activities in which DCLG members are involved are not appropriate for CARRA members and can have a strong impact on what happens to patients. For example, if millions are spent on research and no one has access to the results, this will affect the lives of patients. Ms. Handley also asked for the DCLG's help in understanding what OLA needs to communicate to the advocacy community and professional societies. Ms. Packer would like to address the many wonderful advances that affect so few patients, as this could help ease the overall burden.

Ms. LeStage reported that the date of the next meeting is not clear, but the next teleconference will be scheduled after she talks with Dr. Barker about the DCLG's role in tissue banking.

Ms. LeStage thanked everyone for coming and for showing both patience and impatience with the DCLG's current status, as their impatience serves as a reminder of the many things that remain to be done. Ms. LeStage commended Ms. Giusti for her "fantastic job" in understanding the process that the DCLG must go through and providing the needed leadership. Ms. LeStage also expressed her appreciation and thanks to Ms. Handley, Ms. Lee, Ms. Ghanem, Ms. Hamilton, and Ms. Keisha Martin for planning and executing this meeting, and for their day-to-day support of the DCLG's efforts.

Ms. LeStage expressed her excitement about the survey, which will provide very valuable information to the NCI. The database of organizations will provide Ms. Reed with a list of groups that can provide a response to the NCI's budget. Ms. LeStage firmly believes that the DCLG will emerge from this planning process as a better and stronger group with a truly valuable role to play in the Institute.

XVII. ADJOURNMENT

The meeting adjourned at 12:30 p.m. on January 7, 2003.

Certification

I hereby certify that the foregoing minutes are accurate and complete.

_____	_____
Date	Chair, Director's Consumer Liaison Group
_____	_____
Date	Executive Secretary Director's Consumer Liaison Group

Attachments:
Roster
Reports Cited:

A complete set of handouts is available from the Executive Secretary.

DCLG ACTION ITEMS

January 6-7, 2003

- The DCLG and COPR should explore opportunities for collaboration.
- DCLG members should share suggestions with Dr. Rowland on how to communicate with community physicians about new developments in survivorship.
- Ms. Elaine Lee will e-mail Dr. Julia Rowland's slides to all DCLG members, which they can use as needed in their own presentations.
- DCLG members should share suggestions with Ms. Elisabeth Handley on how to communicate the new CARRA use policy to NCI staff.
- DCLG members should express their appreciation to Dr. Andrew von Eschenbach for his support of CARRA.
- The DCLG will invite Mr. John Hartinger to a future meeting to discuss the NCI's overall budget process.
- Ms. Barbara LeStage will contact Dr. Anna Barker about the DCLG's participation in the tissue banking initiative. Ms. LeStage will schedule the next DCLG teleconference after she talks with Dr. Barker about the DCLG's role in tissue banking.
- OLA will provide more details on the advocacy group survey's time line at the next DCLG meeting.
- The DCLG will continue to work on the advocacy survey.
- The DCLG will continue to provide guidance on the CARRA program.

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